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The Patent Office
Concept House
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Newport
South Wales
NP10 8QQ

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Dated 23 AUG 1999

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Patents Form 1/77

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The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference SPG/PAR.816-2b

2. Patent application number *(The Patent Office will fill in this part)* **9817552.4**

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

JNA Limited
Whitland Abbey
Whitland
Dyfed SA34 0LG

Patents ADP number *(if you know it)* 5377136001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

OPTICAL DEVICE

5. Name of your agent *(if you have one)*

S.P. GILHOLM
WALKER MORRIS
KINGS COURT
12 KING STREET
LEEDS LS1 2HL

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Patents ADP number *(if you know it)* 4373106003

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Patents Form 1/77

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Description	6
Claim(s)	
Abstract	
Drawing(s)	5 + 5

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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature S.P. Gilholm Date 11 August 1998

12. Name and daytime telephone number of person to contact in the United Kingdom

Steve Gilholm
0113 283 2500

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Optical Device

This invention relates to an optical device for monitoring or measuring the arterial oxygen saturation with motion artefact suppression.

Sudden Infant Death Syndrome (SIDS), commonly referred to as cot-death, is defined as the sudden, unexpected death of an apparently healthy infant, usually occurring during sleep, which remains unexplained following a thorough post-mortem examination. It is the most common natural cause of death between the ages of one month and one year. SIDS accounts for about 1,500 deaths in the United Kingdom a year, or four a day. In the United States the figure is 22 deaths a day on average.

At present, the initiating cause or causes of death in SIDS remain undiscovered, and the best that can be achieved is to detect disorders that could be indicative of SIDS. One of the most likely disorders is apnoea - "the cessation of breathing movements for 20 seconds or more" - which can be identified by a monitor. Infants who are considered particularly at risk are siblings, and those prone to apnoea attacks, as well as those born prematurely and of low-birthweight. The now recognised need to monitor these infants continuously has led to the development of a number of apnoea detection systems.

A recent trend has been the introduction of monitoring in the home for infants thought at risk. The monitors currently available to parents measure breathing activity and heart rate. These monitors alarm when there is a prolonged pause in breathing activity and/or a severe fall in heart rate (bradycardia). Despite the commercial success of these monitors their effectiveness in preventing SIDS is now in question. Recent studies reveal that a number of infants die despite surveillance by apnoea monitoring. Thus the need for an effective, non-harmful and more efficient monitoring system is apparent, especially for use in home monitoring.

A number of investigators have reported that the apnoeas and bradycardias which precede SIDS are not primary but are, in fact, secondary to a low blood oxygen level in these infants (hypoxaemia). These investigations showed that more than 80% of these events of severe hypoxaemia occurred well before the development of bradycardia and/or apnoea suggesting that the monitors now commercially available probably alarm too late to be effective in preventing SIDS.

Evidence emerging from current medical research, therefore, points strongly to the desirability of monitoring blood oxygenation rather than breathing movements in infants at risk from SIDS.

Monitors are available which use non-invasive optical techniques to measure the arterial oxygen saturation in patients. As is well known in the art, these instruments suffer interference due to patient movement, motion artefact.

For example, it is known, that in order to measure blood oxygen saturation, it is necessary to provide a device which passes light through biological tissue, such as the human finger, and to monitor the transmitted or reflected output signal from a photodetector of this device continuously. Such devices are described, inter alia, in International Patent Application No. WO94/03102. Movement of the subject leads to a change in the length of the path of the light through the biological tissue and hence to a variation in the intensity of light received by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (eg. oxygen in the blood), and changes in received light intensity caused by variations in the light pathlength due to movement of the subject.

The problem is common to all optical monitoring devices and can render these devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, were continuous monitoring is essential.

We have now devised an optical measuring or monitoring device which is able to monitor or measure the arterial blood oxygen saturation non-invasively and to suppress the effects of motion artefact and which is therefore especially advantageous in the treatment and/or measurement of SIDS.

In accordance with this invention, there is provided a sensor device which comprises light source means for emitting a light beam, optionally of a plurality of at least three different wavelengths. photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelengths received by the photodetector means the arrangement being such that the signal levels corresponding to the different wavelengths bear a predetermined relationship with each other, and signal processing means for processing the actual output signals from the photodetectors to cancel out variations due to motion artefact and to provide an output representing a parameter to be measured or monitored and substantially unaffected by motion artefact.

A particular advantage of the sensor of the invention is that it only enables a user to compare "slopes" on a graph and the use of 3 or more different wavelengths allows for a more accurate determination without an increase in costs. The optimum number of wavelengths is 5 or 6.

The sensor device of the invention is generally an optical measuring or monitoring device.

The sensor may be attached to the chest or abdomen of an infant. The tip of the sensor may incorporate a mirror and is provided with an optical fibre light transmitting cable such that the fibre cable lies flat on the surface of the skin. White light (20 to 50W quartz halogen light bulb) is preferred and is transmitted along an optical fibre to the skin where multiple scattering occurs as photons interact with cellular and subcellular particles. Light can be absorbed by the haemoglobin present in the blood flowing in the tissue below the sensor

before being scattered back along receiving optical fibres. The scattered light can be transmitted along a plurality eg. 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm (green/yellow visible light). Generally, the number of detectors should be the same as the number of transmitting fibres. The sensor may optionally be heated above normal body temperature, to eg. 40°C and up to 42°C for short periods the temperature may even reach 44°C.

According to a further feature of the invention we provide a "hand held" sensor device as hereinbefore described.

In particular, in the "hand held" sensor of the invention the optical fibre transmitting cable(s) may be replaced by a light emitting diode (LED) which significantly reduces the complexity of the sensor.

Before use, the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures. Signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

The use of 6 wavelengths gives the technique a considerable advantage over the pulse oximetry method which uses the minimum number of wavelengths necessary to obtain the information required. The use of more wavelengths in our method gives the technique stability against spurious disturbances at a particular wavelength, enables flexibility in the algorithm to cope with factors such as skin colour. Nevertheless, the sensor of the invention can utilise either oximetry or pulsed oximetry.

Averaging of the signal over a second or more also removes motion artefacts. It is also the case that the technique operates in the visible wavelength range. Thus, although the penetration of light into tissue is much less, the influence of poor contact with the tissue may

also be considerably less thus reducing movement artefact. It is important to emphasise that our technique does not measure pulsatility as is the case in pulse oximetry.

SO_2 is the ratio of the oxyhaemoglobin (HbO_2) concentration to the total concentration of haemoglobin expressed as a percentage.

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

A further important aspect of this invention is the fact that our technique measures arterial blood oxygen saturation. This is achieved in the following way: at normal skin temperature an optical measurement made on the skin of a patient would measure the oxygen saturation of a mixture of venous and arterial blood in the capillaries. In our technique we heat the skin below the sensor to below 40°C. The effect of this application of heat is to cause an increase in skin blood flow, sufficient to cause the oxygen saturation of the blood in the capillaries in the skin to equilibrate with the arterial blood supply. In this way the optical device will measure the equivalent of arterial blood oxygen saturation.

According to a further feature of the invention we provide a method of monitoring of SIDS in infants which comprises attaching a calibrated sensor as hereinbefore described to the skin of a patient and emitting white light, detecting and measuring the scattered light.

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a schematic representation of the optical measurement method of the invention;

Figures 2(a) and 2(b) are both graphs which illustrate how the SO_2 values are

calculated:

Figure 3 is a "hand held" sensor according to the invention;

Figure 4 is a representation of the schematic layout of the optical system of the sensor of the invention; and

Figure 5 is a representation of the hand held sensor of the invention in use.

The measurement technique can best be understood by reference to Figures 2(a) and 2(b). Analysis of the data to obtain an index of haemoglobin concentration and arterial oxygen saturation (SaO_2) is carried out as follows: the gradients between 5 isobestic wavelengths (500, 520, 548, 575 and 586 nm) are added to given an index which is related to the haemoglobin concentration. This index is used to normalise the measured tissue spectra. The oxygen saturation (SO_2) is calculated from the gradients between the absorption peaks for de-oxygenated haemoglobin (560 nm) and the two adjacent isobestic wavelengths (548 and 575 nm) of the normalised spectra.

The most important factor influencing the stability of the SaO_2 lies in our 6 wavelength analysis technique which incorporates the 5 isobestic wavelengths and the single oxygenated/deoxygenated peak. The two accompanying Figures illustrate how the HbI and SO_2 values are obtained from the spectra. HbI is the modulus of the slopes of the lines connecting the isobestic points as shown in the first Figure 2(a): it can be seen that any change in the general level of the signal, such as may occur due to small changes in the distance of the probe from the skin would not have any significant influence on this value. The absorption spectrum may shift up or down, but the modulus of the slope remains constant.

SO_2 values (Figure 2(b)) are calculated from the modulus of the slopes of the extinction values between the neighbouring isobestic points and the deoxygenated peak. normalised to the HbI value. We thus obtain not only an SO_2 value but, on the way, we can also obtain a measure of relative haemoglobin concentration (HbI) from our measurements.

FIGURE 1

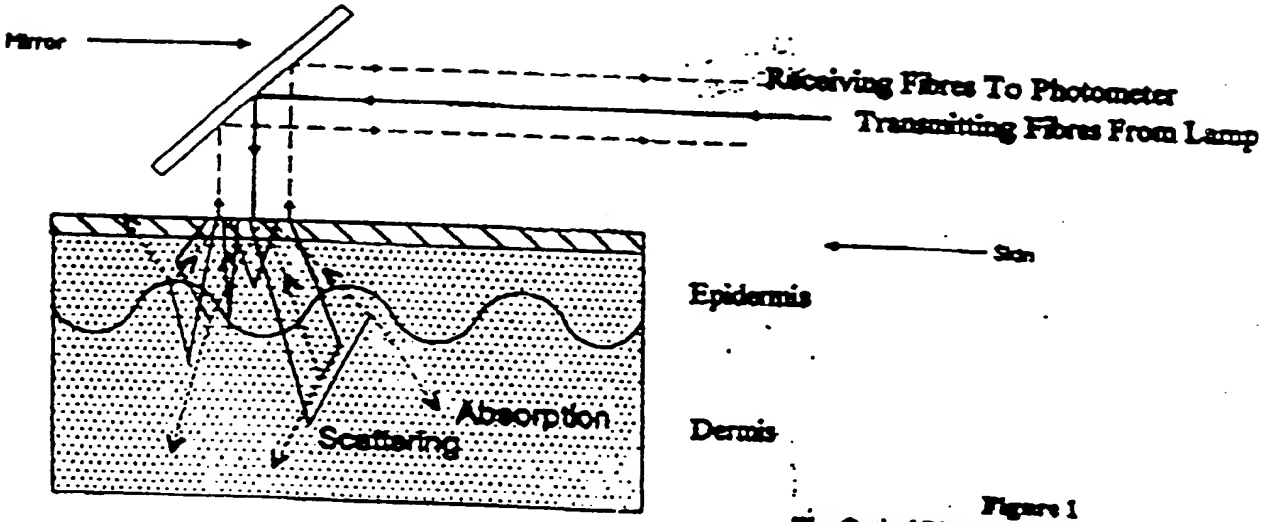

Figure 1
The Optical Blood Oxygen Saturation Sensor

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FIGURE 2

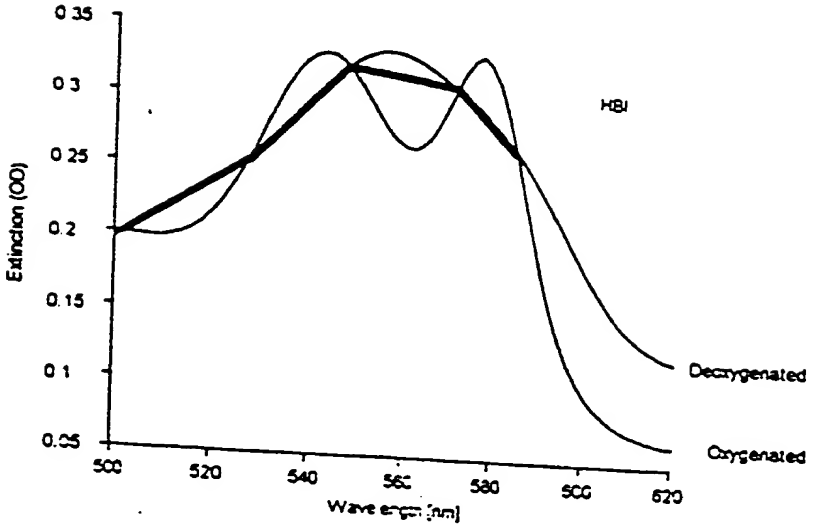

Figure 2(a)

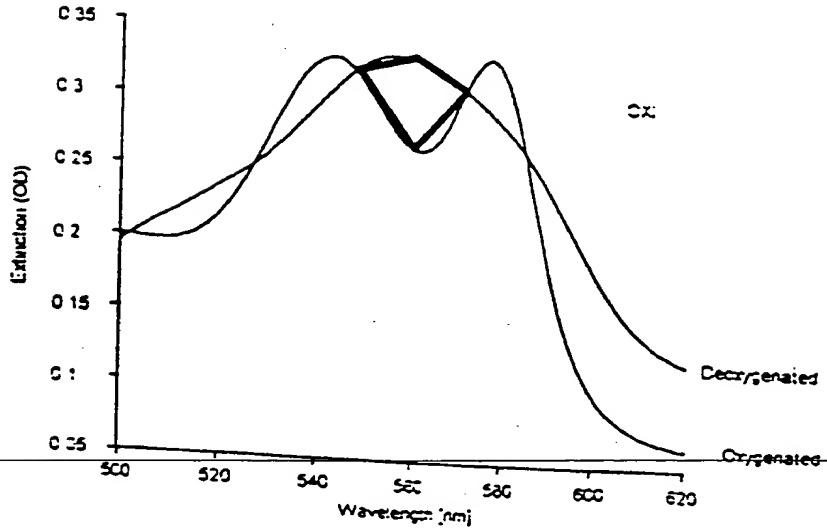

Figure 2(b)

FIGURE 3

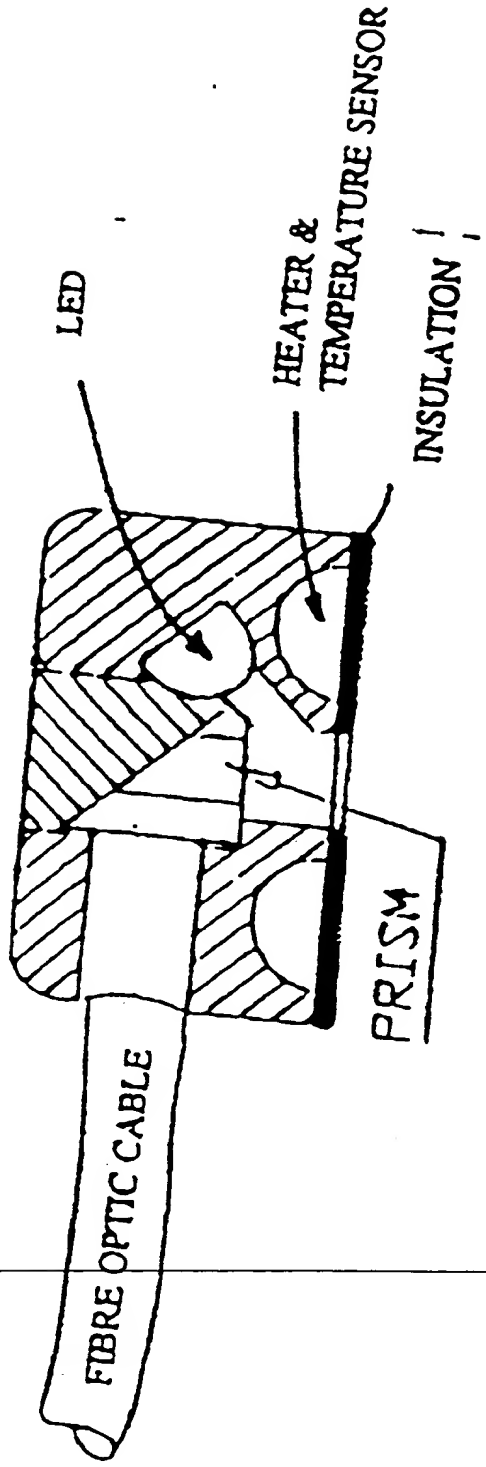
LED
HEATER & TEMPERATURE SENSOR
INSULATION
PRISM
FIBRE OPTIC CABLE

FIGURE 4

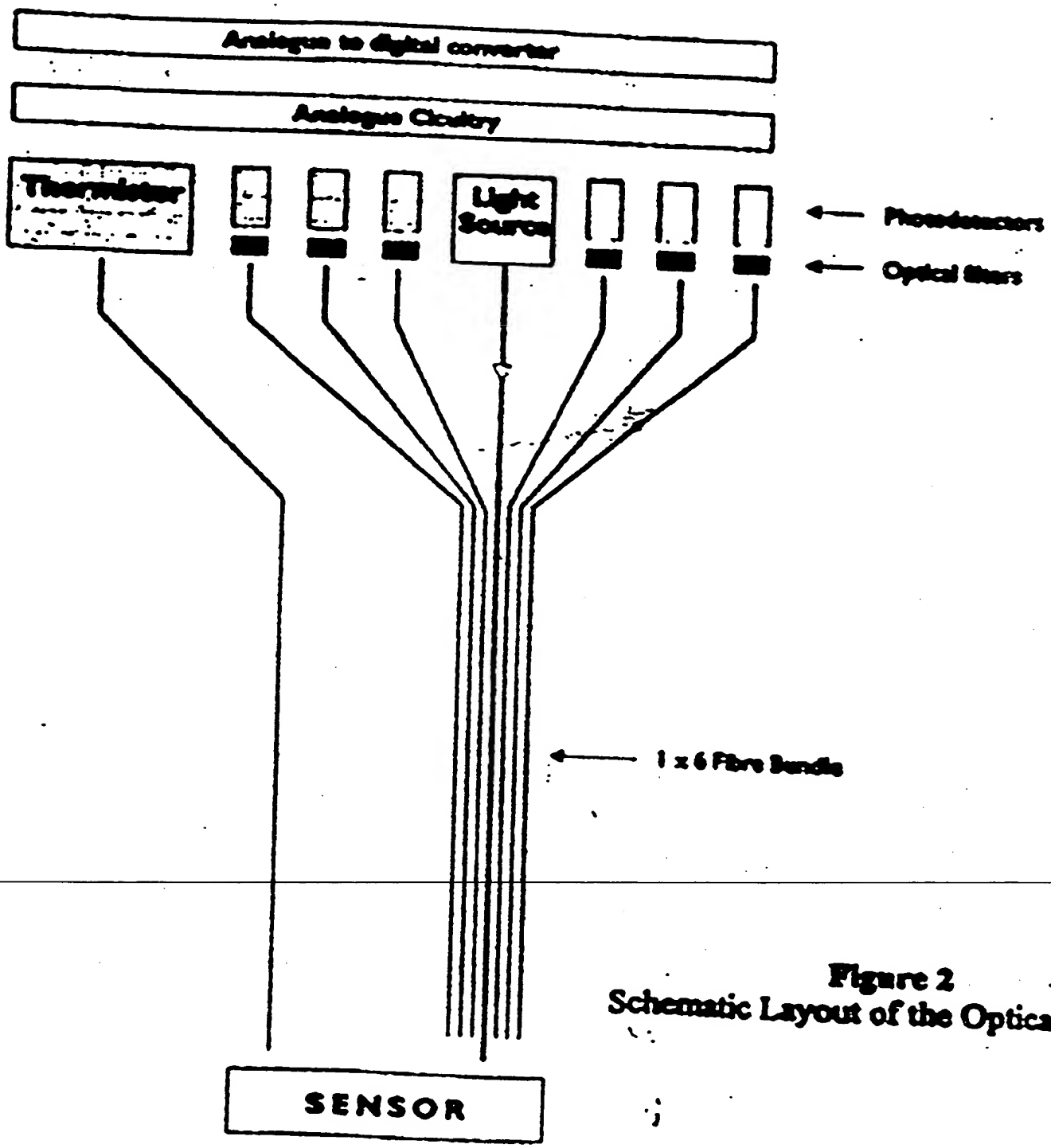

Figure 2
Schematic Layout of the Optical Syster

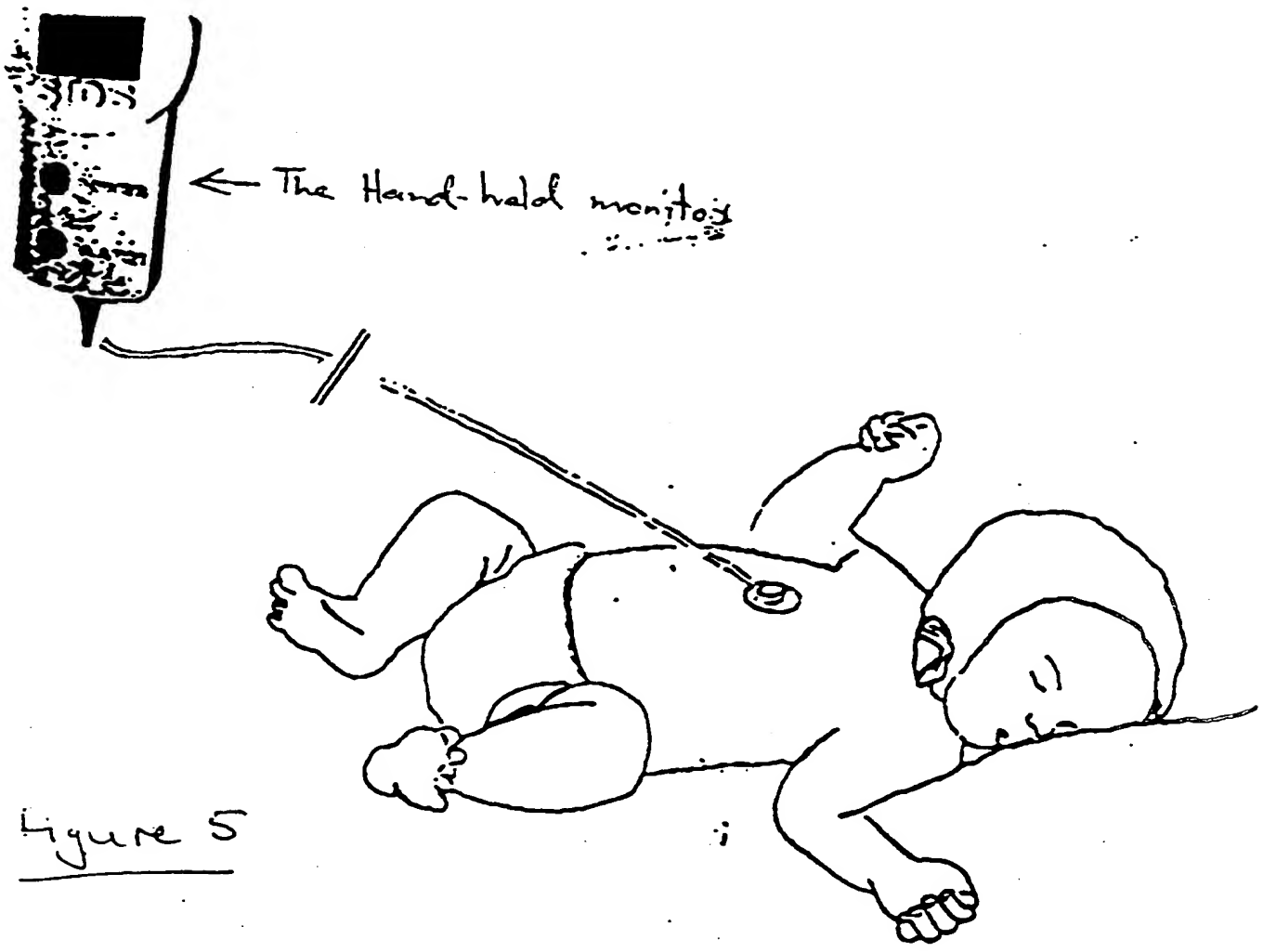

Figure 5

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Harrison Goddard Foote